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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,838	02/08/2002	Jing Li	018781-007610US	1366
7590 09/23/2005 BANNER & WITCOFF 1001 G STREET N.W. WASHINGTON, DC 20001			EXAMINER UNGAR, SUSAN NMN	
			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,838

Applicant(s)

LI ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-20 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 10-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 44 is/are allowed.
- 6) ☐ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>Copy 055222 9/6/2002</u> | 6) <input type="checkbox"/> Other: _____ |

1. The Amendment filed June 20, 2005 in response to the Office Action of February 28, 2005 is acknowledged and has been entered. Previously pending claims 21-43 have been cancelled, claims 1, 2, 4, have been amended and new claim 44 has been added. Claims 1-9, 44 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

Claim Rejections - 35 USC 112

4. Claims 1-9 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed February 28, 2005, Section 6, pages 5-8.

Applicant argues that the claims have been amended to recite polypeptide comprising at least 95% identity to SEQ ID NO:2 and that such sequences include polymorphic variants. Further, the rejection provides no evidence or reasoning that one of skill could not reasonably expect PCR techniques to be applicable to polymorphic variants of SEQ ID NO:2.

The argument has been considered but has not been found persuasive as the claims are not limited to polymorphic variants and SEQ ID NO:2 is not amenable to PCR techniques since it is not a nucleic acid. The arguments have been considered but have not been found persuasive and the rejection is maintained.

5. Claims 1-9 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed February 28, 2005, Section 6, pages 8-13.

Applicant argues that written description does not require that the disclosure as originally filed provide in haec verba support for the claimed subject matter and

points to *Purdue Pharma L.P.V. Faulding Inc.* and argues further that it is not necessary that the application describe the claim limitations exactly, but only to the extent that one of ordinary skill in the art would recognize from the disclosure that appellants invented the subject matter and points to *In re Herschler*. The arguments have been considered but have not been found persuasive because Applicant has presented no explanation of why the case-law is relevant to the instant rejection or how the issues raised in the cited cases are analogous to the instant rejection.

Applicant argues that the claims meet the requirements of *Lilly*, cited previously, in that Applicants have provided a structural feature, that is that the claimed sequences have 95% identity to the reference sequence, which relates to highly conserved variants or polymorphic alleles. The argument has been considered but has not been found persuasive because neither the specification nor the claims teach which 95% of the reference sequence is claimed and the claims are not drawn to either highly conserved variants or polymorphic alleles.

Applicant further argues that the claims as filed and amended recite structural hallmarks, sequences that amplify and/or hybridize to the sequence to be detected and a reference polypeptide sequence. The argument has been considered but has not been found persuasive because the identity of the amplifiers and/or hybridizers is unknown in view of the 95% identity language for the reasons of record.

Applicant further argues that the MPEP states that if an applicant discloses an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. The argument has been considered but has not been found persuasive because the issue raised is not drawn to degenerate sequences, but rather the issue raised is to nucleic acids that

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encode PRC17 polypeptides comprising at least 95% amino acid sequence identity to SEQ ID NO:2.

The arguments have been fully considered but have not been found persuasive and the rejection is maintained.

6. Claim 44 appears to be free of the art and allowable.

7. Applicant's amendment necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

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Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

A handwritten signature in black ink, appearing to read "Susan Ungar", is written over the printed name.

Susan Ungar
Primary Patent Examiner
August 22, 2005